REMARKS AND ARGUMENTS

Claim amendments

Claim 1 has been amended to recite that in the fat base composition of the invention the total palmitic acid residues content is at most 38% of the total fatty acid residues and at least 60% of the fatty acid residues at the sn-2 position of the glycerol backbone are palmitic acid residues; and 6-17% of the unsaturated fatty acid residues at the sn-1 and sn-3 positions are linoleic acid residues and/or 40-60% of the unsaturated fatty acid residues at the sn-1 and sn-3 positions are oleic acid residues.

Support for this claim can be found in the description and in claims 16 and 17 (now both canceled).

New claim 20 has been added. Support for this claim can be found in the description and in claim 1 and claims 16 and 17 (both now canceled).

It is respectfully submitted that the amendments do not introduce any new subject matter.

Claim Rejections - 35 USC § 112

1-3. The Examiner rejected claims 5, 6, 16 and 17 under 35 USC § 112. In view of the amendments to claim 1, these claims were canceled.

Claim Rejections - 35 USC § 103

7. The Examiner rejected claims 1-10, 13-17 and 19 are as being unpatentable over US Patent No. 4,876,107 (King et al.) in view of Innis et al. (American Institute of Nutrition, 1995), both previously made of record.

8. The Examiner states with regard to claim 1-3 and 9 that King teaches an enzymatically prepared fat base composition comprising a mixture of vegetable derived triglycerides, because King teaches a substitute milk fat composition for use in feeding young mammals and especially infants (Col. 1, lines 7-8), thus deemed a substitute human milk fat composition and an infant formula, and teaches various embodiments of the fat base composition (Blends 1-4, Table 3) wherein the total palmitic acid residues content is at most 38% of the total fatty acid residues because King teaches embodiments wherein the palmitic acid residues are between 26-33% of the total fatty acid composition of the blends (Table 3, % of 16:0 in Blends 1-4). King further teaches that at least half of the fatty acid residues at the sn-2 position are C16 and/or C18 saturated, preferably consisting substantially of palmitic acid, particularly 60-90% by weight of the total sn-2 fatty acids (col. 2, lines 25-29). King teaches that such an arrangement results from the rearrangement of vegetable fat via enzymes (Col. 3, lines 20-25). King further teaches that milk replacement fats should match the performance of milk fat as closely as possible in order to reproduce its physical and dietary characteristics and teaches that human milk fat consists of a variety of triglycerides of both saturated and unsaturated fatty acids (Col. 1, lines 13-18). King further teaches that the proportions of infant formulations have been adjusted from time to time in an effort to develop a formula more nearly approximating to mother's milk (Col. 1, lines 25-27).

With regard to the Examiner's assertion above, it is to be noted that Blends 1-4 of King (Tables 2 and 3) **are not** as the Examiner wrote *fat base compositions* (as claimed in claim 1), they are *blends*. The equivalents in King of the fat base composition of present claim 1 are the "samples" (Table 1 of King). Fat bases (samples) have different fatty acids composition, they are not approximates of human milk fat, they are just structured fat concentrates, and they are not suitable for use directly in infant formulas. Fat bases can only be used as ingredients of infant formulas after mixture (blending) with other oils, by which blends are created which include more fatty acids, and have a fatty acids composition suitable for use as the fat component of infant formulas.

It is important to note that even if this approach of comparing fat base with blend (which is practically irrelevant) was adopted, also the blends of King et al. differ from the present fat base (as defined in claim 1 and its dependent claims and in claim 20), for example because the palmitic acid level at sn-2 position, out of total sn-2 fatty acids, is not >60% as in claim 1 or because they do not have 6-17% of the unsaturated fatty acid residues at the sn-1 and sn-3 positions being linoleic acid residues and/or 40-60% of the unsaturated fatty acid residues at the sn-1 and sn-3 positions being oleic acid residues as in claims 1 or 20. So it is not clear whether the Examiner is comparing the composition of the final product, or the composition of the starting material (fat base + oil/s). In any event, to avoid any further issues, although the novelty rejections were withdrawn, the claims were amended so as to distinguish the fat base of the invention not only from the parallel "samples" of King, but also from its blends.

9. The Examiner appreciates that King does not specifically teach embodiments of the enzymatically prepared fat base composition where both the total palmitic acid residues are at most 38% of the total fatty acid residues, and at least 60% of the fatty acid residues at the sn-2 position of the glycerol backbone are palmitic acid residues.

It is to be noted that King also does not teach the compositions of claim 1 as amended or of new claim 20, and of their dependent claims.

10. The Examiner then turns to Innis and states that this document teaches that palmitic acid represents 20-30% of the fatty acids in human milk and pig milk, and around 70% of this palmitic acid are esterified to the sn-2 position of the milk triacylglycerol (Col. 1, lines 1-5).

11. Therefore, the Examiner concludes that Innis teaches the composition of human milk and King teaches that it is known and beneficial to develop infant formulas that approximate the fatty acid profile of mother's milk in order to reproduce its physical and dietary characteristics, and King further teaches various embodiments of the fat base

composition that possesses the fatty acid profile taught by Innis, which meets the fatty acid profile of claim 12.

12. Therefore, the Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention, for the enzymatically prepared fat base of King to have the claimed composition of fatty acids, because King teaches embodiments that possess the claimed amount of total palmitic acid residues and the amount of palmitic acid present at the sn-2 position of the glycerol backbone, and teaches the importance of developing infant formulas that possess a fatty acid profile that approximates mother's milk and Innis teaches the specific fatty acid profile of human milk from the perspective of the amount of palmitic acid residues. Therefore, one of ordinary skill in the art would have been motivated by both King and Innis to develop a fat base composition for use in infant formulas that approximates, as close as possible, the palmitic acid profile of human milk in order to provide a suitable substitute to human milk for infants.

Applicants respectfully traverse.

First of all it is important to understand the structural differences between the fat base of present claim 1, particularly as amended, and the fat base (samples) and blends of King and the rearranged triacylglycerols of Innis (which is a blend). To facilitate this understanding, below are the comparative data:

	Current application	King							Innis
	Amended	Samples (table 1)			Blends (table 3)				Rearranged
	Claim 1	1	2	3	1	2	3	4	TG (table 1)
Total palmitic acid residues	<38%	44.5%	40%	40%	33%	26%	30%	30.5%	29.6%
Palmitic acid at sn-2 position of total sn-2 fatty	>60%	80%	80%	80%	57%	41%	56%	57%	69.9%

acids									
Palmitic acid at sn-2 position of total palmitic acid	**<70%**	59.9%	66.7%	66.7%	57.6%	52.6%	62.8%	62.3%	78.7%
Oleic acid of total unsaturated fatty acids at sn-1 and sn-3	**40-60%**	81.3%	100%	80.8%	74.1%	61.9%	81.3%	73.7%	67.7%
Linoleic acid of total unsaturated fatty acids at sn-1 and sn-3	**6-17%**	**10.5%**	0%	**11.7%**	20%	20%	20%	20%	26.8%

	Current application	**Applicant COAs**							
	Amended Claim 1	**8149146**	**8158024**	**8151590**	**8151592**	**8151593**	**8151594**	**8151595**	**8150671**
Total palmitic acid residues	<38%	29.8%	30.1%	28.9%	29.5%	29.5%	30.6%	30.4%	28.5%
Palmitic acid at sn-2 position of total sn-2 fatty acids	>60%	56.6%	57.1%	53.5%	55.9%	55.9%	56.8%	57.8%	52.7%
Palmitic acid at sn-2 position of total palmitic acid	<70%	63.3%	63.2%	61.7%	63.2%	63.2%	61.9%	63.4%	61.6%
Oleic acid of total unsaturated fatty acids at sn-1 and sn-3	40-60%	87.4%	85.1%	85.7%	86.2%	86.2%	86%	85.5%	86.9%
Linoleic acid of total unsaturated fatty acids at sn-1 and	6-17%	12.6%	14.5%	13.8%	13.6%	13.6%	14%	14.3%	13%

sn-3									

The data in the Table were calculated as follows:

Total palmitic acid residues: the values are taken from the respective tables in King and Innis.

Palmitic acid at sn-2 position of total sn-2 fatty acids: the values are taken from the tables in King and Innis.

Linoleic acid and oleic acid of total unsaturated fatty acids at sn-1 and sn-3:

For the samples and blends from King the only calculation is:

Total linoleic at sn-1,3 (value from table)/the total unsaturated fatty acids at sn-1,3 [the sum of C16:1, C18:1 and C18:2 at sn-1,3 (from table)]*100 = 11.5/(3+41.5+11.5)*100 = 20%

For the rearranged triglycerides from Innis the calculation is:

1. Calculate the ratio of the fatty acids at sn-2 position: fatty acid at sn-2 position of total sn-2 position (from table)/3/total fatty acid (from table)*100, for example

   The ratio of the oleic acid at sn-2 = 13.7/3/40.6*100=11.2%

   The ratio of the linoleic acid at sn-2 = 6.5/3/16.4*100=13.2%

   The ratio of the linolenic acid at sn-2 = 0.8/3/3.2*100=8.3%

2. Calculate the ratio of the fatty acids at sn-1,3 position: 100% – (the ratio at sn-2), for example

   The ratio of the oleic acid at sn-1,3 = 100-11.2%=88.8%

   The ratio of the linoleic acid at sn-1,3 = 100-13.2%=86.8%

   The ratio of the linolenic acid at sn-1,3 = 100-8.3%=91.7%

3. Calculate the percentage of the fatty acids at sn-1,3 position of total fatty acids at sn-

1,3: (the ratio at sn-1 and sn-3)/100*3/2*(the % of total the fatty acid (from the table), for example:

The oleic at sn-1 and sn-3: 88.8/100*3/2*40.6 = 54.1%

The linoleic at sn-1 and sn-3: 86.8/100*3/2*16.4 = 21.4%

The linolenic at sn-1 and sn-3: 91.7/100*3/2*3.2 = 4.4%

4. Calculate the total linoleic at sn-1,3 (from table) from the total unsaturated fatty acids at sn-1,3:
total linoleic at sn-1,3 (from table) / the total unsaturated fatty acids at sn-1,3 [the sum of C16:1, C18:1 and C18:2 at sn-1,3 (from table)]*100, for example:

The oleic at sn-1,3 of total unsaturated at sn-1,3 =54.1/(54.1+21.4+4.4)*100=67.7%

The linoleic at sn-1,3 of total unsaturated at sn-1,3 =21.4/(54.1+21.4+4.4)*100=26.7%

The linolenic at sn-1,3 of total unsaturated at sn-1,3 =4.4/(54.1+21.4+4.4)*100=5.5%

The inventors wish to point out that when studying the data in Tables 1 and 2 in Innis et al., as below, for easy reference:

Innis 1995 (cites Innis 1993 as reference for the rearranges TG)

	Total fatty acids					sn-2 Position fatty acids				
		Formula					Formula			
Fatty acid	Sow milk	MCT[2] oil	Coconut oil	Palm oil	Rearranged triacylglycerols	Sow milk	MCT oil	Coconut oil	Palm oil	Rearranged triacylglycerols
	g/100 g									
8:0	0.1	22.2	3.3	0.5	0.6	–	23.7	–	–	–
10:0	0.2	8.2	1.9	0.4	0.4	–	9.3	0.9	–	–
12:0	0.2	0.6	19.1	3.3	0.7	0.7	0.1	24.6	4.0	4.7
14:0	3.1	0.1	6.8	2.1	1.8	4.5	–	3.1	0.7	4.7
16:0	30.7	4.3	6.5	27.0	29.6	55.3	0.4	1.3	4.4	69.9
18:0	4.4	3.0	3.4	5.6	3.1	4.0	0.4	–	0.6	2.6
18:1	40.4	40.8	39.0	40.0	40.6	18.7	40.6	41.5	59.5	13.7
18:2[n-6]	8.2	16.2	15.6	16.4	16.4	4.9	22.3	23.2	25.1	6.5
18:3[n-3]	0.8	3.4	3.2	3.1	3.2	0.3	5.2	5.5	5.4	0.8

Innis 1993

TABLE 1
Fat composition of formulas with various saturated fatty acid compositions and structures and sow milk*

Fatty acids	Formula				Sow milk
	MCT	Coconut oil	Palm oil	Synthesized triglyceride†	
			%		
8:0	22.2	3.2	0.5	0.6	0.1 ± 0.0‡
10:0	8.2	1.9	0.4	0.4	0.2 ± 0.0
12:0	0.6	19.1	3.3	3.3	0.2 ± 0.0
14:0	0.1	6.8	2.1	1.8	3.1 ± 0.3
16:0	4.3	6.5	27.0	29.6	30.7 ± 2.7
18:0	3.0	3.4	5.6	3.1	4.4 ± 0.2
18:1n−9	40.8	39.0	40.0	40.6	40.4 ± 3.8
18:2n−6	16.2	15.6	16.4	16.4	8.2 ± 0.1
18:3n−3	3.4	3.2	3.1	3.2	0.8 ± 0.0
20:0	0.4	0.3	0.6	0.4	0.1 ± 0.0
20:1	0.5	0.4	0.4	0.1	0.4 ± 0.0
22:0	0.1	0.2	0.1	0.1	0.1 ± 0.0

TABLE 2
Fatty acid composition of the *sn*-2 position of formulas and sow milk triglycerides

Fatty acids	Formula				
	MCT *	Coconut oil	Palm oil	Synthesized triglyceride†	Sow milk
			%		
8:0	23.7	—	—	—	—
10:0	9.3	0.9	—	—	—
12:0	0.1	24.6	4.0	4.7	0.7
14:0	—	3.1	0.7	1.7	4.5
16:0	0.4	1.3	4.4	69.9	55.3
18:0	0.4	—	0.6	2.6	4.0
18:1n−9	40.6	41.5	59.5	13.7	18.7
18:2n−6	22.3	23.2	25.1	6.5	4.9
18:3n−3	5.2	5.5	5.4	0.8	0.3

* Medium-chain triglyceride.
† Betapol (Loders Croklaan, The Netherlands).

Thus, the data presented in Table 1 of Innis 1995 (cited as prior art in the OA) appear to have some evident mistakes; the total fatty acids sum being less than 100% and the sn-2 position fatty acids sum being more than 100% (marked in bold fonts in the table below, rightmost column, last line, **102.9%**). Further, trying to calculate the ratio of C12 at sn-2 position (the fatty acid at sn-2 position of the total same fatty acid), seem to be not logical. Therefore, the inventors looked at the data at Innis 1993, which is cited for the rearranged triglyceride. The comparison is shown in the table below:

	Innis 1993		Innis 1995	
Fatty acid	total	sn-2	total	sn-2
8	0.6		0.6	
10	0.4		0.4	
12	3.3	4.7	0.7	4.7
14	1.8	1.7	1.8	4.7
16	29.6	69.9	29.6	69.9
18	3.1	2.6	3.1	2.6
18:1	40.6	13.7	40.6	13.7
18:2	16.4	6.5	16.4	6.5
18:3	3.2	0.8	3.2	0.8
20	0.4			
20:01	0.1			
22:00	0.1			
sum	99.6	99.9	96.4	**102.9**

Comparing the data from both references might indicate a possible typing mistake at Innis 1995. Therefore, the calculations were performed according to the data presented in Innis 1993. Even calculating according to the data in Innis 1993 the rearranged triglyceride has different composition than the one in claim 1 or 20.

In any event, with the data at hand, it can be clearly seen that the fat base compositions of the invention differ from those of King, and that combining with Innis would not make them similar to those of King.

Moreover, not only would any fat base composition resulting from the combination of King and Innis be different from that of present claims 1 and 20, it would not solve the problem of cost, as outlined in the introductory part of the specification, and in the previous amendment. Like King, also Innis shows a rearranged fat base composition which is prepared by interesterifying a tripalmitin-rich fraction of palm oil with free fatty acids from vegetable oils (see page 74, right hand column, lines 13-15). Palm oil, and in particular its tripalmitin-rich fraction, are very expensive starting material.

Thus, it is to be borne in mind that a main object of the invention is not merely to provide human milk fat approximates, but to provide cost-effective such approximates, as ingredients for preparing fat blends that can be used a substitutes of human milk fat in infant foods, particularly formulas (e.g. page 9, line 6; page 21, paragraph 3 of the international publication).

The fat bases of the present invention can be used in relatively low amounts, to yield blends that are suitable as human milk fat substitutes. Thus, for example, the lowest amount of fat base (sample) used in King is 50% (Table 2, Blend 2). If this blend of King in compared, for example, with the blend using 30% fat base in the present application (see e.g., Example 2, InFat 1 (page 17); page 24, table of the international publication), according to market values of the starting materials the cost of production of a blend suitable as human milk fat substitute using 50% fat base instead of only 30%, would be raised by more than 40%. Other advantages of the fat base of the invention when used in blends are presented in Example 3 and Table 2, comparing to commercially available fat bases (Concentrates 1 and 2). Generally, the cost of the fat base is 4 times higher than the cost of the blending oils, therefore reducing the amount of the fat base highly affects the cost of the blend, which is the ingredient of the infant formula.

Infant formulas are produced for mass consumption. Keeping their cost reasonable for all sections of the population is important, however cost-effectiveness should not in any manner result in lower quality, and any potential damage to the consuming infant. It is this need that is answered by the present invention.

It is therefore respectfully submitted that the invention is not obvious over King in view of Innis.

13. With regard to claims 4-6, the Examiner stated that King in view of Innis teach that sn-1 and sn-3 positions include unsaturated fatty acids, preferably largely consisting of oleic and linoleic acid, and further teaches that at least 70% of the fatty acid residues at the sn-1 and sn-3 positions are oleic and other unsaturated fatty acid

residues, because King in view of Innis teach that the combination of the invention, as detailed in the Office Action.

Applicant respectfully traverses, if but for the fact that claim 4 depends on claim 1, which has been discussed in detail above. Claims 5 and 6 have been canceled.

It is therefore respectfully submitted that the fat base of claim 4 is not obvious over King in view of Innis.

14. With regard to claims 7 and 8, the claimed blends employ the fat base of the invention. The advantages of using the fat base of the invention as a constituent of a fat ingredient (blend) for preparing infant formulas have been demonstrated above.

It is therefore respectfully submitted that the blends of claims 7 and 8 are not obvious over King in view of Innis.

15-18. Claims 10, 13, 14, 15, 17 and 18, are all dependent claims, and therefore the above arguments apply.

19-21. The Examiner stated with regard to claim 19 that King and Innis do not specifically teach that the substitute human milk fat composition comprises blending with 50-75% of at least one vegetable oil, and that the amount of vegetable oil to be added is obvious in order to provide the ideal fatty acids composition. The Examiner also states that in view of claim 7, the amount of vegetable oil is not critical.

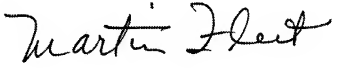
Applicants respectfully traverse in view of the arguments above. The blends of the invention are not obvious, inter alia because they use the fat base of the invention, which enables the use of very small amount of fat base for achieving a useful fat blend, with high cost-effectiveness, and demonstrated above.

22-28. The rejection of claims 11, 12 and 18 on King et al, in view of Innis et al, and further in view of Cooper is entirely based on hindsight using applicants claimed invention as the basis to build the rejection. None of these references disclose, teach or even suggest the limitations of these claims. Accordingly, it is respectfully that the rejection be reconsidered and withdrawn.

Reconsideration and withdrawal of the rejections are respectfully solicited and requested. In light of the foregoing remarks, this application should be in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

Further, it is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time, time sufficient, to effect a timely response, and shortages in this or other fees, be charged, or any overpayment in fees be credited, to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 7056-X08-022)

Respectfully submitted,



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